



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,708	05/03/2005	Michael Birsha Davies	P33143USW	6207

23347 7590 09/05/2008
GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B482
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

3771

NOTIFICATION DATE

DELIVERY MODE

09/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM

LAURA.M.MCCULLEN@GSK.COM

JULIE.D.MCFALLS@GSK.COM

Office Action Summary

Application No.

10/533,708

Applicant(s)

DAVIES ET AL.

Examiner

CLINTON OSTRUP

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 14-33 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 14-33 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is in response to the amendment filed May 30, 2008. As directed by the amendment, claims 1, 12, 14, and 17 have been amended; claims 11, 13 and 34-35 have been cancelled, and new claims 36-39 have been added. Thus, claims 1-10, 12, 14-33, and 36-39 are pending in this application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 6, 8-10, 12, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dmitrovic et al., (WO 98/30262).

Dmitrovic et al., teach a container (Figure 3) having a first part (59) and a second part (63) and a hinge (64) through which the first and second parts are hingeably connected so that the parts are hingeable relative to one another between a first position (closed) which places the container in a closed state and a second position (open) which places the container in an open state, and wherein the first and second parts are pivotally connected so that the parts are able to be pivoted relative to one another to different angular positions with the first part configured to be pivotal to a first angular position disposed behind the second part and the first part and the second part configured to nest together in a nesting state (when the dust cap is rotated 180 degrees

and flipped up onto the body) when the first part is in the first angular position. See: page 9, lines 19-25 and figures 3-5.

Although Dmitrovic discloses a container that has a first part and a second part that can be pivoted and rotated relative to one another, Dmitrovic lacks the specific teaching that the first part and second part are configured to be nested together. Since Dmitrovic teaches that "it will be appreciated that this angle (the angle between the dust cap and lower body and the mouthpiece) can be substantially increased or slightly decreased according to the desired angle Of rotation of the dust cover, lower body potion and dosing member" and the dust cover is capable of being flipped up toward the rear of the body, it would have been an obvious modification to one having ordinary skill in the art to rotate the lower body portion and dust cover 180 degrees from the mouth piece and then flip the dustcover upward to form a compact, easy to hold container that nests the body inside the dust cover while delivering medicament to a user.

Dmitrovic et al., show the first and second parts as being closed (Figure 3) with a ridge portion on (80) for locking the container in a closed state, thus meeting the limitations of claims 2, 3, and 6.

In regard to claims 8-10, 12 & 19, Dmitrovic et al., shows that the second part (63) as being pivotally hinged to the first part (59). The Dmitrovic et al., reference teaches that the hinge is statically mounted to the first part (59) and pivotally mounted to the second part (63) and that the first and second parts can pivot and rotate around the container (Figure 4). Dmitrovic et al., teach moving the second part to both an open and a closed state and that in use, in the open position, the second part (63) is rotated

to the side of the container (Figure 5) to allow administration of the drug contained within the container. See: page 4, line 21 -page 5, line 8 and page 11, line 23 – page 12, line 9.

Dmitrovic et al., teach that the drug is contained in an inner part (56) and that the inner part (56) is adapted to hold the product in the container, thus meeting the specific limitations of claim 19. See: page 4, line 21 - page 5, line 21.

4. Claims 4, 5, 7, 21, 24-27, 30-33 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (6,062,214) and further in view of Dmitrovic et al., (WO 98/30262) as applied to claims 1-3, 6, 8-13, 16 and 19 above.

Howlett teaches an inhaler for the aerosolized dispersion of medicaments. The primary reference teaches an inhaler comprising a housing (11) for receiving a pressurized dispensing container (12) and a mouthpiece (14) with a flexible hinged cover (15) that can potentially come into contact with the face of the user during normal use. See: figure 3. The primary reference teaches the lip of the cover (15) making contact with the lip of the mouthpiece (14) to close and protect the mouth piece. See: Col. 2, lines 55-65; col. 3, lines 17-21 and Figure 1. However, the reference lacks the specific hinge claimed as claimed in claims 21, 24-27 and 30-33.

Dmitrovic et al., teach a container (Figure 3) having a first part (59) and a second part (63) and a hinge (64) through which the first and second parts are hingeably connected so that the parts are hingeable relative to one another between a first position which places the container in a closed state and a second position which places the container in an open state, and wherein the first and second parts are

pivotaly connected so that the parts are able to be pivoted relative to one another to different angular positions. See: page 10, line 16 – page 11, line 5; Figures 3-8; and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the aerosol housing with a mouthpiece cover as taught by Howlett, by using the hinged cover as taught by Dmitrovic et al., because of the reasonable expectation of obtaining a cover that would not come into contact with the face of the user during regular use.

Regarding claims 36-39, when the dust cap on the inhaler device is turned 180 degrees from the mouthpiece and the dust cap is flipped upwards, it would provide a concave/convex nesting state as claimed with the dust cap slidable engaging the body (as it makes contact with the body), and friction would provide an interference between the dust cap and body. See: figures 3-5 and page 9, line 20 - page 10, line 2.

5. Claims 14, 15, 17, 18 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (6,062,214) taken together with Dmitrovic et al., (WO 98/30262) and further in view of Rand et al., (WO 98/56444).

The combined references above teach a container for holding an aerosol that has a cover that can be opened and pivoted in a manner to prevent contamination during normal use, as described above; however, the combination of references lacks the specific teaching of providing a container with reading feature and dose counter as claimed in claims 14, 15, 17, 18 and 29 or the intranasal dispenser as claimed in claim 28.

Rand et al., teach an inhaler comprising an external housing (1) with counter mechanism (13) and a window for viewing said counter mechanism through the rear of the housing (20). The Rand et al., reference teaches that the dispensing mechanism is useful in the treatment of respiratory disorders and that the counter allows the user to view the number of doses remaining in the container before the contents have been exhausted. Moreover, the Rand et al., reference teaches that metered dose inhalers are well known for delivering medicaments to the mouth and the nose for treatment of respiratory disorders. See: page 1, lines 1-34; page 4, lines 1-9; page 5, lines 24-35; page 6, lines 26-33 and Figures 1 and 7.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the aerosol device as taught by the combined references above by adding a viewing window for reading the number of doses remaining in the inhaler, as taught by Rand et al., because of the reasonable expectation of obtaining an inhaler which provides a user with information about the remaining life of the product.

Response to Arguments

6. Applicant's arguments, filed May 30, 2008, regarding claims 1-3, 6, 8-10, 12, 16 and 19 have been fully considered but they are not persuasive.

Applicant argues that Dmitrovic does not disclose a container having a first part configured to be pivotal to a first angular position disposed behind the second part and the first part and the second part configured to nest together in a nesting state when the first part is in the first angular position.

The examiner respectfully disagrees. First, it should be remembered that the claims only require that the device be configured with the first part configured to be pivotal to a first angular position disposed behind the second part and the first part and the second part configured to nest together in a nesting state when the first part is in the first angular position. Dmitrovic appreciates that the angle of rotation of the dust cover can be substantially increased (page 9, line 20 - page 10, line 2) and if the dust cover is rotated 180 degrees from the mouthpiece, and the cover is flipped upwards, then the device of Dmitrovic is configured to have a first part (59) configured to be pivotal (either 59 or 63 can be pivoted) to a first angular position (when the 63 is opened and rotated 180 degrees) disposed behind the second part and the first part and the second part configured to nest together (by flipping up the dust cover) in a nesting state when the first part is in the first angular position.

7. Applicant's arguments filed May 30, 2008, regarding the 35 USC 103(a) rejection of claims 4, 5, 7, 21, 24-27 and 30-33 as being unpatentable over Howlett in view of Dmitrovic (WO 98/30262), have been fully considered but they are not persuasive.

Applicant argues that neither Howlett nor Dmitrovic disclose, teach or suggest that a first part and a second part of a container are configured to nest together in a nesting state when the first part is in the first angular position and that the examiner has used impermissible hindsight to create the combination.

As described above, Dmitrovic was used to teach a device that is configured to have a first part (59) configured to be pivotal (either 59 or 63 can be pivoted) to a first angular position (when the 63 is opened and rotated 180 degrees) disposed behind the

second part and the first part and the second part configured to nest together (by flipping up the dust cover) in a nesting state when the first part is in the first angular position.

8. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).
9. Applicant's arguments filed May 30, 2008, regarding the 35 USC 103(a) rejection of claims 14, 15, 17, 18 and 28-29 as being unpatentable over Howlett in view of Dmitrovic (WO 98/30262) and further in view of Rand et al., (WO 98/56444), have been fully considered but they are not persuasive.

Applicant argues that Rand does not disclose, teach or suggest that a first part and a second part of a container are configured to nest together in a nesting state when the first part is in the first angular position.

As described above, Dmitrovic was used to teach a device that is configured to have a first part (59) configured to be pivotal (either 59 or 63 can be pivoted) to a first angular position (when the 63 is opened and rotated 180 degrees) disposed behind the second part and the first part and the second part configured to nest together (by

flipping up the dust cover) in a nesting state when the first part is in the first angular position.

10. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771